

**WHAT IS CLAIMED IS:**

1. A method of improving the diagnostic performance of a probe system for detecting a medical condition in a patient, which probe system includes at least one probe to be applied to a measurement site of the patient for sensing volume or volume-related changes in a monitored body part thereat due to pulsatile arterial blood flow in the body part, characterized in calibrating said probe system for the respective measurement site of the respective patient according to a predetermined characteristic of said monitored body part of the patient, and quantifying the arterial pulsatile volume thereat.

2. The method according to Claim 1, wherein said predetermined characteristic of the monitored body part includes the relative volume of the tissue therein.

3. The method according to Claim 1, wherein said probe includes a pressure sensor which senses said volume changes by sensing changes in pressure in a compressible fluid system of volume  $V_F$  when applied to said monitored body part and of volume  $V_S$  where not applied to said body part, said body part including a fixed volume  $V_T$  of non-compressible tissue and a pulsatively-variable volume  $V_P$  corresponding to arterial volume changes, such that the pressure in said compressible fluid system changes with the change in pulsatile volume thereof and the gain of said changes varies according to the relative values of the volumes  $V_T$  and  $V_F$ .

4. The method according to Claim 2, wherein the relation values of the volumes  $V_T$  and  $V_F$  are determined by:

determining the volume  $V_S$  of said compressible fluid system when it is not applied to the body part;

determining the volume  $V_F$  of the compressible fluid system when it is applied to the body part;

and subtracting  $V_F$  from  $V_S$  to produce the volume  $V_T$  of the non-compressible tissue.

5. The method according to Claim 4, wherein the volume  $V_S$  of the compressible fluid system when it is not applied to the monitored body part is determined by:

measuring the pressure ( $P_1$ ) of said volume  $V_S$  of the compressible fluid system when it is not applied to the monitored body part;

introducing into said compressible fluid system a known calibrating volume ( $V_C$ ) of the compressible fluid;

measuring the pressure ( $P_2$ ) of said volumes  $V_F$  and  $V_C$ ;

and determining the volume  $V_S$  of the compressible fluid system according to the following equation:

$$V_S = P_2 \cdot V_C / (P_1 - P_2) \quad (\text{Eq. 1})$$

6. The method according to Claim 5, wherein the volume  $V_S$  of said compressible fluid system when it is not applied to the monitored body part is determined by:

introducing said compressible fluid into the compressible fluid system at a known rate;

measuring the time taken for the pressure in the compressible fluid system to reach a predetermined value;

and integrating said known rate over said measured time.

7. The method according to Claim 5, wherein the effective volume  $V_F$  of the compressible fluid system when it is applied to the monitored body part and effective volume  $V_T$  of the non-compressible tissue is determined by:

measuring the pressure ( $P_1$ ) of the volume  $V_F$  of the compressible fluid system when it is applied to the monitored body part;

measuring the pressure  $P_2$  of the volumes  $V_F$  and  $V_C$  of the compressible fluid system after introducing said calibration volume  $V_C$ ;

determining the volume  $V_F$  of the compressible fluid system when it is applied to the monitored body part according to the following equation:

$$V_F = P_2 \cdot V_C / (P_1 - P_2) \quad (\text{Eq. 2})$$

and determining the volume  $V_T$  of the non-compressible tissue according to the following equation:

$$V_T = V_S - V_F \quad (\text{Eq. 3})$$

8. The method according to Claim 7, wherein said probe outputs a pulsatile signal corresponding to said sensed arterial volume changes  $V_P$ , and wherein said pressures  $P_1$  and  $P_2$  are  $P_{\min}$  and  $P_{\max}$  taken, respectively, at the lowest and highest points of the pulsatile signals outputted by said probe.

9. The method according to Claim 8, wherein the pulse volumes  $V_P$  are determined according to the following equation:

$$V_P = (P_1 - P_2) \cdot V_{\min} / P_2 \quad (\text{Eq. 4})$$

wherein:  $V_{\min} = V_T$ ; and  $P_1 = P_{\min}$  and  $P_2 = P_{\max}$ .

10. The method according to Claim 9, wherein said pulse volumes  $V_P$  are multiplied by the fraction  $K/V_T$  ( $K$  being a constant), and are used as an index of pulse size corrected for the tissue volume of the respective patient.

11. The method according to Claim 7, wherein the method further includes verifying the accuracy of the measured volume of the pulsatile signal corresponding to said sensed arterial volume changes  $V_P$  by repeating the foregoing operations while applying the compressible fluid system, instead of to the body part, to a physical model of a known fixed volume having the ability of generating pulses of defined volume.

12. The method according to Claim 5, wherein the probe system is calibrated while the temperature and barometric pressure are measured at the time of calibration, and during subsequent measurements, and all derived volumes are expressed in terms of a set of predetermined standard conditions of atmospheric pressure and temperature.

13. The method according to Claim 12, wherein said probe is calibrated by means including:

a pressure sensor;

a pump for introducing said compressible fluid into the compressible fluid system of the probe system from a calibrated volume generating source;

and a data processor for determining the total added volume and the time taken for the pressure in the compressible fluid system to reach a predetermined pressure value.

14. The method according to Claim 13, wherein said calibrated volume generating source, said pressure sensor, and said data processor maintain a constant

pressure within said probe system, such that volume changes generated by the said calibrated volume generating source are equal in size but opposite in direction to volume changes in said monitored body part due to pulsatile arterial blood flow in the monitored body part.

15. The method according to Claim 1, wherein:

said probe includes an optical sensor having a light source and a light receiver;

and wherein said probe is calibrated for the respective patient by the use of a model which modifies said light source to produce in said light receiver a waveform simulating that produced by the pulsatile arterial blood flow in the monitored body part of the respective patient.

16. The method according to Claim 15, wherein said model includes a light-transmissive body illuminated by said light source, and a function generator for generating a waveform to drive said light source such as to produce in said light receiver a waveform simulating that produced by the pulsatile arterial blood flow in the monitored body part of the respective patient.

17. The method according to Claim 16, wherein said model includes:

a porous light-transmissive matrix simulating the vascular bed of the non-compressible tissue in the monitored body part of the respective patient;

a liquid light-absorbing medium;

and a pump for pumping said liquid light-absorbing medium through said porous matrix in a manner analogous to the pulsatile arterial blood flow through the monitored body part of the respective patient.

18. The method according to Claim 1, wherein said monitored body part is a finger, toe or distal portion of a limb of the patient, and said probe encloses said body part such as to monitor the peripheral arterial tone thereof.

19. Apparatus for detecting a medical condition of a patient, comprising:

a probe system including a probe to be applied to a measurement site of the patient for sensing volume or volume-related changes in a monitored body part thereat due to pulsatile arterial blood flow in the body part;

and calibrating means for calibrating said probe system for the respective measurement site, according to a predetermined physical characteristic of the body part of the respective patient, and for quantifying the arterial pulse volume thereat.

20. The apparatus according to Claim 19, wherein said predetermined characteristic of the monitored body part includes the relative volume of the tissue therein.

21. The apparatus according to Claim 19, wherein said probe includes a pressure sensor which senses said volume changes by sensing changes in pressure in a compressible fluid system of volume  $V_F$  when applied to said monitored body part and of volume  $V_S$  where not applied to said body part, said body part including a fixed volume  $V_T$  of non-compressible tissue and a pulsatively-variable volume  $V_P$  corresponding to arterial volume changes, such that the pressure in said compressible fluid system changes with the change in pulsatile volume thereof and the gain of said changes varies according to the relative values of the volumes  $V_T$  and  $V_F$ .

22. The apparatus according to Claim 21, wherein said calibrating means includes a data processor programmed to determine the volume  $V_S$  of the compressible fluid system according to the following equation:

$$V_S = P_2 \cdot V_C / (P_1 - P_2) \quad (\text{Eq. 1})$$

wherein:

$P_1$  is the pressure of the compressible fluid system, of volume  $V_F$ , when it is not applied to the monitored body part;

$V_C$  is the volume of a known calibrating volume of compressible fluid added to the compressible fluid system after measuring pressure  $P_1$ ;

and  $P_2$  is the pressure of the compressible fluid system after said volume  $V_C$  of calibrating fluid has been added thereto.

23. The apparatus according to Claim 22, wherein said data processor is programmed to determine the volume  $V_T$  of the non-compressible tissue according to the following equations:

$$V_F = P_2 \cdot V_C / (P_1 - P_2) \quad (\text{Eq. 2})$$

$$V_T = V_S - V_F \quad (\text{Eq. 3}).$$

24. The apparatus according to Claim 23, wherein said probe outputs a pulsatile signal corresponding to said sensed arterial volume changes  $V_P$ , and wherein said data processor is programmed to measure said pressures  $P_1$  and  $P_2$  at the lowest and highest points  $P_{\min}$  and  $P_{\max}$ , respectively, of the pulsatile signal outputted by said probe.

25. The apparatus according to Claim 24, wherein said data processor is programmed to determine the pulse volumes ( $V_P$ ) according to the following equation:

$$V_P = (P_1 - P_2) \cdot V_{\min} / P_2 \quad (\text{Eq. 4})$$

wherein:  $V_{\min} = V_T$ ; and  $P_1 = P_{\min}$  and  $P_2 = P_{\max}$ .

and said pulse volumes, when multiplied by the fraction  $K/V_T$  ( $K$  being a constant), thereby serving as an index of pulse size corrected for the tissue volume of the respective patient.

26. The apparatus according to Claim 25, wherein the apparatus further comprises temperature and barometric pressure testers, and wherein said data processor is programmed to convert all derived volumes in terms of predetermined standard conditions of atmospheric pressure and temperature.

27. The apparatus according to Claim 22, wherein said calibrating means includes:

a pump of known stroke volume for each cycle;

a counter for counting the number of cycles for introducing said compressible fluid into the compressible fluid system at a known rate;

and a data processor for determining the total added volume and the time taken for the pressure in the compressible fluid system to reach a predetermined pressure value.

28. The apparatus according to Claim 22, wherein said calibrating means includes:

a pump for introducing said compressible fluid into the compressible fluid system of the probe from a supply of constant (or known) rate of flow of fluid;

means for determining the time interval of flow of the fluid into the compressible fluid system of the probe;

and a data processor for determining the total added volume and the time taken for the pressure in the compressible fluid system to reach a predetermined pressure value.

29. The apparatus according to Claim 32, wherein said calibrating means includes:

a pump for introducing said compressible fluid into the compressible fluid system of the probe from a calibrated volume generating source;

and a data processor for determining the total added volume and the time taken for the pressure in the compressible fluid system to reach a predetermined pressure value.

30. The apparatus according to Claim 29, wherein said calibrated volume generating source, said pressure sensor, and said data processor maintain a constant pressure within said probe system, such that volume changes generated by the said calibrated volume generating source are equal in size but opposite in direction to volume changes in said monitored body part due to pulsatile arterial blood flow in the monitored body part.

31. The apparatus according to Claim 19, wherein said probe system includes an optical sensor having a light source and a light receiver; and wherein said apparatus further includes for calibrating the probe system for the measurement site of the respective patient, a model which modifies said light source to produce in said light receiver a waveform simulating that produced by the pulsatile arterial blood flow in the body part of the respective patient.

32. The apparatus according to Claim 31, wherein said model includes a light-transmissive body illuminated by said light source, and a function generator for generating a waveform to drive said light source such as to produce in said light receiver a waveform simulating that produced by the pulsatile arterial blood flow in the body part of the respective patient.

33. The apparatus according to Claim 31, wherein said model includes:

a porous light-transmissive matrix simulating the vascular bed of the non-compressible tissue in the body part of the respective patient;

a liquid light-absorbing medium;

and a pump for pumping said liquid light-absorbing medium through said porous matrix in a manner analogous to the pulsatile arterial blood flow through the body part of the respective patient.

34. The apparatus according to Claim 19, wherein said probe is configured and dimensioned to monitor the peripheral arterial tone of the monitored body part.

35. The apparatus according to Claim 34, wherein said calibrating means includes a physical model of a shape similar to that of the body part, and of an adjustable volume which is presettable according to the volume of the body part to receive the probe.

36. The apparatus according to Claim 35, wherein said physical model further includes means for effecting predetermined pulsatile volume changes.

37. The apparatus according to Claim 35, wherein said physical model includes an outer elastic envelope enclosing a plurality of model sections displaceable relative to each other to change the volume defined by said elastic envelope.

38. The apparatus according to Claim 37, wherein said physical model further includes a rotatable cam assembly effective to displace said model sections by the rotation of said cam assembly.

39. The apparatus according to Claim 37, wherein said physical model further includes an inflatable bladder effective to displace said model sections by the inflation of said bladder.

40. The apparatus according to Claim 35, wherein said physical model includes an inflatable external elastic envelope for adjusting the volume of the model by the inflation of said bladder according to the physical characteristics of the body part of the respective patient.